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**PPE REGULATION 2016/425 – ANNEX V
MODULE B – EU TYPE EXAMINATION
ASSESSMENT REPORT**

Respiratory protective device

Report n°	19.0197
Technical referential	EN 140:1998
Type of device	PPE category III Half mask
Model	XPG702

Fontaine, the 10/12/2019

Report sent for the attention of Maggie Zhong to the email addresses below:
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This report includes 14 pages

The technical assessment manager
Immaterial original

BARBETHA

Validation électronique

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1.Introduction - Description of the service

This assessment report concerns PPE category III – Half mask as defined in EN 140:1998.

Its purpose is to assess the conformity of the PPE with the PPE REGULATION 2016/425, with a view to be placed on the European market exclusively.

The assessment was conducted in accordance with purchase order signed on 21/01/2019 placed by SHANGHAI MAGIC DEVELOPMENT for the count of XIAMEN CHENGHUANG AUTOMOTIVE MATERIAL CO, LTD.

Company: XIAMEN CHENGHUANG AUTOMOTIVE MATERIAL CO, LTD. – 2/F, No 39 Xinchang Road – Xinyang Industrial Zone – Haicang District - XIAMEN – China 361000

2.Use of the report

This assessment report only concerns the equipment identified in clause 4 and described in clause 7.

Only an integral reproduction of this assessment report is authorized.

The manufacturer, or his representative, commits himself not to use this assessment report for equipment that is not strictly identical to the equipment covered by this re assessment report.

3.Economical operator(s)

XIAMEN CHENGHUANG AUTOMOTIVE MATERIAL CO, LTD. – 2/F, No 39 Xinchang Road – Xinyang Industrial Zone – Haicang District - XIAMEN – China 361000

4.Identification of the equipment

Model: XPG702

5.Conditions for use of the equipment

A half mask is a facepiece which covers the nose, mouth and chin. It is intended to provide adequate sealing on the face of the wearer of a respiratory protective device against the ambient atmosphere, when the skin is dry or moist and when the head is moved. This half mask is intended to be use as part of respiratory protective devices, except escape apparatus and diving apparatus.

6.Reference specification

The assessment of conformity with Regulation 2016/425 of 9th march 2016 "Personal Protective Equipment" was conducted taking into account the provisions of European standard EN 140:1998 "Respiratory protective device – Half masks and quarter masks".

7. Technical Documentation

7.1. Identification

Identification of the assessed Technical Documentation:

1. Authorized representative – Company: Mr Li Linfeng - XIAMEN CHENGCHUANG AUTOMOTIVE MATERIALS CO, LTD.
2. Commitment signature date: 15/10/2019, last update received the 05/12/2019
3. Technical Documentation reference: not applicable

7.2. Drawing



7.3.Description

Twin filter half mask in polycarbonate equipped with a harness in polyethylene with two adjustable elastic webbing in polyester and rubber linked behind the neck by hooks, and an exhalation valve in silicon. The filters are fitted on the half mask with two bayonet connectors including two inhalation valves in silicon. Size M.

7.4.Description of components

Detailed description of components in the Technical Documentation.

7.5.CE Marking

× Notified body in charge of assessment control to article 19c) of PPE regulation (module C2 or D):

APAVE SUDEUROPE SAS - France

× CE mark: **CE 0082**

× Graphic of letters C and E: **Conform**

× Height of mark: **5mm**

× Marking clear and permanent: **Conform**

× Location of the marking: **On the breathing valve cover**

7.6.Packaging

Month and year of obsolescence is indelibly and unambiguously marked on the packaging

8. Correlation between the articles of PPE Regulation 2016/425 and the reference standard

The following table shows the correlation between the essential health and safety requirements of Regulation 2016/425 of 9th march 2016 "Personal Protective Equipment" and the articles of the European standard EN 140:1998 "Respiratory protective device – Half masks and quarter masks".

PPE Regulation 2016/425 Annex II	Clauses of the standard
1.1.1	6.16, 6.18
1.1.2.1	6.10, 6.11, 6.16, 6.18
1.2.1	6.4, 6.5, 6.6, 6.18
1.2.1.1	6.4, 6.5, 6.6, 6.13
1.2.1.2	6.18
1.2.1.3	6.16, 6.18
1.3.1	6.10, 6.18
1.3.2	6.10.3, 6.11.2
1.4	9
2.1	6.10, 6.18
2.3	6.16
2.4	8, 9
2.6	6.4
2.8	9
2.9	6.8, 6.9
2.12	8
3.10.1	6.6, 6.12, 6.14, 6.15, 6.18, 9

WARNING: Other requirements and other EU Directives maybe applicable to the products falling within the scope of this European Standard.

9.Examination report

Article of the standard EN 140	Content	Conformity *			Comments
		Yes	No	N-A	
Art. 6	Requirements				
Art 6.4	Materials The use of aluminium, magnesium and titanium or alloys containing such proportions of these metals as will, on impact, give rise to frictional sparks capable of igniting flammable gas mixtures for exposed parts, i.e. those which may be subjected to impact during use of the apparatus shall be restricted to a minimum.	✓			
Art 6.5	Resistance to temperature Following the temperature conditioning and after being allowed to return to ambient temperature the facepiece shall show no appreciable deformation and any incorporated connector to prEN 148.1 shall be gauged and shall comply with the appropriate standard. After this test the facepiece shall meet the requirements for inward leakage as specified in 6.16.	✓			Date of tests: 29/07/2019
Art 6.6	Flammability Parts of the facepiece that might be exposed to a flame during use shall either not burn or not continue to burn for more than 5 s after removal from the flame. It is not required that the facepiece still has to be useable after the test.	✓			Date of tests: 20/09/2019
Art 6.7	Cleaning and disinfecting The materials used shall withstand the cleaning and disinfecting agents and procedures as recommended by the manufacturer.	✓			
Art 6.8	Demountable parts All demountable connections shall be readily connected and secured, where possible by hand. Any means of sealing used shall be retained in position when the connection is disconnected during normal maintenance.	✓			

* The measurement uncertainties are not taken into account for the assessment of conformity.

Article of the standard EN 140	Content	Conformity *			Comments
		Yes	No	N-A	
Art 6.9	Replaceable components Unless integral with the half mask or quarter mask the following components (if fitted) shall be replaceable: Head harness, connector(s), inhalation and exhalation valves.	✓			Date of tests: 19/09/2019
Art 6.10	Head harness				
Art 6.10.1	The head harness shall be designed so that the facepiece can be donned and removed easily.	✓			
Art 6.10.2	The head harness shall be adjustable or self-adjusting and shall hold the facepiece firmly and comfortably in position.	✓			
Art 6.10.3	Each strap of the head harness, buckles and other adjusting means shall withstand a pull of 50 N applied for 10 s in the direction of pulling when the facepiece is donned. No breaks or sliding of the straps shall occur.	✓			
	The requirement applies to the buckles and attachment tugs as well as to the straps.	✓			
Art 6.11	Connector				
Art 6.11.1	The connection between the facepiece and the apparatus may be achieved by a permanent or special (e.g. insert) type of connection or by a thread connection to EN 148-1.	✓			
Art 6.11.1.1	A facepiece shall not have more than one thread connection to EN 148-1.	✓			
	If more than one connector is fitted the design of the facepiece or of the remainder of the equipment shall be such that the use of different types or combinations of respiratory protective devices does not present a risk.	✓			
Art 6.11.1.2	If any other screw thread is used it shall not be possible to connect it directly to the thread to EN 148-1.			✓	Date of tests: 19/09/2019
Art 6.11.1.3	Half masks and quarter masks shall not be equipped with a thread connection to EN 148-2.	✓			
Art 6.11.2	The connection between the faceblank and the connector shall be sufficiently robust to withstand axially a tensile force of 50 N.	✓			
Art 6.11.3	Correct and reliable connection between facepiece and other parts of the equipment shall be assured.	✓			

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Article of the standard EN 140	Content	Conformity *			Comments
		Yes	No	N-A	
Art 6.12	Inhalation valves and exhalation valves				
Art 6.12.1	General				
	Valve assemblies shall be such that they can be readily maintained and correctly replaced.	✓			
	It shall not be possible to fit an exhalation valve assembly into the inspiratory circuit or an Inhalation valve assembly into the exhalation circuit.	✓			
	Inhalation and exhalation valve assemblies, sub-assemblies and piece parts that are by the manufacturer designed to be identical, are acceptable.			✓	
	Differently designed inhalation and exhalation valves are acceptable If a precise and comprehensible description is given in the information manual supplied by the manufacturer. The description in the information manual supplied by the manufacturer should be supported by illustrations (photographs, drawings) on how to assemble the unit correctly.	✓			
	To enable correct assembly, the parts have to be precisely and comprehensibly described or marked.	✓			
	An appropriate method of checking correct assembly shall be described, e.g. visual inspection; check by the wearer; test by maintenance personnel etc.	✓			
Art 6.12.2	Inhalation valve				
Art 6.12.2.1	The facepiece should preferably be provided with one or more inhalation valve(s). If a thread connection to EN 148-1 is used, an inhalation valve shall be incorporated in the facepiece. Where the facepiece is intended to be used with filters it shall be provided with an integral inhalation valve, if there is no valve in the filter.	✓			
Art 6.12.2.2	Inhalation valves shall function correctly in all orientations and shall meet the requirements of 6.15.	✓			Read §6.15

* The measurement uncertainties are not taken into account for the assessment of conformity.

Article of the standard EN 140	Content	Conformity *			Comments
		Yes	No	N-A	
Art 6.12.3	Exhalation valve				
Art 6.12.3.1	Exhalation valves shall function correctly in all orientations and shall meet the requirements of 6.15.	✓			Read §6.15
Art 6.12.3.2	The facepiece shall have at least one exhalation valve or appropriate means to allow the escape of exhaled air and, where applicable, any excess air delivered from a supplied air source.	✓			
Art 6.12.3.3	Exhalation valves (if fitted) shall be protected against or be resistant to dirt and mechanical damage. They may be shrouded or include any other device that may be necessary to comply with 6.16.	✓			
Art 6.12.3.4	Exhalation valves shall continue to operate correctly after a continuous exhalation flow of 300l/min over a period of 30s and meet the requirements of 6.15.	✓			Date of tests: 12/09/2019
Art 6.12.3.5	When the exhalation valve housing is attached to the faceblank, it shall withstand axially a tensile force of 50N applied for 10s.			✓	
Art 6.13	Compatibility with skin Materials that can come into contact with the wearer's skin shall not be known to be likely to cause irritation or any other adverse effect to health.	✓			Manufacturer statement
Art 6.14	Carbon dioxide content of Inhalation air The carbon dioxide content of the inhalation air (dead space) shall not exceed an average of 1.0 % (by volume).	✓			Date of tests: 13/09/2019 $CO_{2max} \leq 0,71\%$
Art 6.15	Breathing resistance The breathing resistance of the facepiece shall not exceed 2,0 mbar for inhalation and 3,0 mbar for exhalation when tested with a breathing machine (25 cycles/min, 2,0 l/stroke) or a continuous flow of 160 l/min.	✓			Date of tests: 12/09/2019 At 160l/min : $R_{INHAL} \leq 1,15$ mbar $R_{EXHAL} \leq 2,45$ mbar
	The inhalation resistance shall not exceed 0.5 mbar at 30 l/min continuous flow and 1.3 mbar at 95 l/min continuous flow..	✓			$R_{INHAL30l/min} \leq 0,33$ mbar $R_{INHAL95l/min} \leq 0,75$ mbar



* The measurement uncertainties are not taken into account for the assessment of conformity.

Article of the standard EN 140	Content	Conformity *			Comments
		Yes	No	N-A	
Art 6.16	Inward leakage When the facepieces are fitted in accordance with the information supplied by the manufacturer, at least 46 out of the 50 individual results for the inward leakage over each of the exercise periods (i.e. 10 subjects x 5 exercise periods) shall be not greater than 5%. and, in addition, at least 8 Out of the 10 individual wearer arithmetic means (10 subjects) for the inward leakage, averaged over all exercise periods shall be not greater than 2%	✓			Date of tests: 10/10/2019 50 results ≤ 5%
Art 6.17	Field of vision The field of vision shall be subjectively assessed for acceptability.	✓			10 averages ≤ 2%
Art 6.18	Practical performance The complete apparatus shall undergo practical performance tests under realistic conditions. These general tests serve the purpose of checking the equipment for imperfections that cannot be determined by the tests described elsewhere in this European Standard. Where practical performance tests show the apparatus has imperfections related to wearer's acceptance, the test house shall provide full details of those parts of practical performance tests which revealed these imperfections. This will enable other test houses to duplicate the tests and assess the results thereof. Here are the comments of tests subjects: a) Harness comfort b) Security of fastenings and couplings c) Accessibility of controls (if fitted) d) Clarity of vision e) Field of vision (to be determined with the component to be used directly on the facepiece) f) Any other comment reported by the wearer on request	✓		✓	Read §6.18 Date of tests 10/10/2019 No comments No comments No comments No comments No comments
				✓	No comments

* The measurement uncertainties are not taken into account for the assessment of conformity.

Exercise	Test subject reference									
	1	2	3	4	5	6	7	8	9	10
Walk	1,280	1,352	1,356	0,160	0,040	1,018	0,826	0,057	0,040	1,044
Left-Right	1,670	1,282	1,712	0,239	0,082	1,126	1,214	0,075	0,028	1,257
Up-Down	1,293	1,009	0,578	0,166	0,069	1,493	0,891	0,060	0,029	1,320
Alphabet	2,005	1,980	0,848	0,238	0,053	1,459	2,622	0,057	0,024	0,756
Walk	1,621	1,190	0,676	0,248	0,074	1,378	1,074	0,062	0,034	0,091
average	1,574	1,363	1,034	0,210	0,064	1,295	1,325	0,062	0,031	0,894

Inward leakage values in %

Article of the standard EN 140	Content	Conformity			Comments
		Yes	No	N-A	
Art. 8	Marking				
Art 8.1	Facepiece				
Art 8.1.1	The manufacturer shall be identified by name, trade mark or other means of identification.	✓			
Art 8.1.2	All units of the same model shall be provided with a type-identifying marking.	✓			
Art 8.1.3	Size (if more than one size is available).			✓	
Art 8.1.4	The number and the year of this European Standard.	✓			
Art 8.1.5	Where the reliable performance of components may be affected by ageing, means of identifying the date (at least the year) of manufacture shall be given.	✓			
	For parts which cannot reasonably be marked e.g. straps of head harness, the relevant information shall be included in the information supplied by the manufacturer.	✓			
Art 8.1.6	Parts which are designed to be replaced by the authorized user and sub-assemblies with considerable bearing on safety shall be readily identifiable.			✓	
	For parts which cannot reasonably be marked e.g. straps of head harness, the relevant information shall be included in the information supplied by the manufacturer.			✓	
Art 8.1.7	The marking shall be clearly visible and durable.	✓			
Regulation	CE Marking (CE + Notified body in charge of module C2 or D) ;	✓			
	The CE marking shall be affixed visibly, legibly and indelibly to the PPE ;	✓			
	For PPE subject to ageing: the month and year of manufacture and/or, if possible, the month and year of obsolescence must be indelibly and unambiguously marked on each item of PPE placed on the market and on its packaging ;	✓			
	Name and address of the manufacturer ;	✓			
	Type, batch or serial number or other means of identification	✓			
Art 8.2	Packaging				
Art 8.2.1	The manufacturer shall be identified by name, trade mark or other means of identification.	✓			
Art 8.2.2	Type-identifying marking.	✓			
Art 8.2.3	Size (if more than one size is available).	✓			
Art 8.2.4	The number of this European Standard.	✓			
Art 8.2.5	Attention shall be drawn to the information supplied by the manufacturer by the following pictogram:	✓			
					
Art 8.2.6	The end of shelf life may be indicated e. g. by the following pictogram:	✓			
					

Article of the standard EN 140	Content	Conformity			Comments
		Yes	No	N-A	
	<i>Concerning the instruction for use: Only the English version has been checked. It is the responsibility of the manufacturer to supply the instruction for use in the official languages of the country of destination</i>				
Art. 9	Information supplied by the manufacturer				
Art 9.1	On delivery information shall accompany every facepiece.	✓			
Art 9.2	The information shall be in the official language(s) of the country of destination.	✓			
Art 9.3	The information shall contain all information necessary for trained and qualified persons on: <ul style="list-style-type: none"> - application/limitation; - checks prior to use; - donning, fitting; - use; - cleaning/disinfection; - maintenance (preferably separately printed instructions); - storage; - shelf life or equivalent. 	✓ ✓ ✓ ✓ ✓ ✓ ✓ ✓			
Art 9.4	The information shall be precise and comprehensible. If helpful, illustrations, part numbers, marking shall be added.	✓			
Art 9.5	Warning shall be given against problems likely to be encountered, for example: <ul style="list-style-type: none"> - fit of facepiece (check prior to use); - it is unlikely that the requirements for leakage will be achieved if facial hair passes under the face seal; - hazards of oxygen and oxygen-enriched air; - air quality; - use of equipment in explosive atmosphere. 	✓ ✓ ✓ ✓ ✓			
Regulation	Name and address of the manufacturer;	✓			
	Name, address and identification number of the notified body or bodies involved in the conformity assessment of the PPE (module B and module C2 or D) ;	✓			
	EU declaration of conformity or the internet address where the EU declaration of conformity can be accessed ;	✓			
	The risk against which the PPE is designed to protect ;	✓			
	The reference to this Regulation	✓			
	The references to the relevant harmonised standard(s) used, including ;	✓			
	The date of the standard(s), or references to the other technical specifications used ;	✓			

10. Conclusion

The PPE category III – Half mask identified in paragraph 4 meets the Essential Health and Safety Requirements of PPE Regulation 2016/425 of 9th march 2016.

The assessment of conformity takes into account the compliance of the PPE with the provisions of European standard EN 140:1998, and with the conformity of manufacturer's technical documentation.

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